510(k) Summary of Safety and Effectiveness

DEC 07 2007

OnePort® Surgical Trocar System

K073009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter

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Date Prepared

August 31, 2007

Name of Device

OnePort® Surgical Trocar System

Classification Names

Endoscope and accessories

Device Classification

Regulatory Class:	Class II
Product Code:	GCJ
Classification Panel:	General & Plastic Surgery Obstetrics/Gynecology
Regulation Number:	21 CFR 876.1500

Predicate Devices

K924761	Reflex STR Trocar System	Richard-Allan Medical Industries
K933456	ConMed TroGard™ Blunt Tip Trocar System	ConMed Corporation
K952977	SABRE™ Multi-Use Trocar System	Endoscopic Concepts, Inc.
K001697	ConMed TroGARD® Finesse™ Trocar System	ConMed Corporation

Description of Device

The OnePort® Surgical Trocar System is a range of surgical trocars and accessories intended for use as a means of providing abdominal access for various instruments during laparoscopic, pelviscopic, and thoracoscopic surgery. The OnePort® Surgical Trocar System is available in four configurations:

- Fully disposable with Bladed Trocar
- Fully disposable with Dilating Trocar
- Reposable Cannula with Bladed Trocar (reusable cannula, disposable trocar and seal)
- Reposable Cannula with Dilating Trocar (reusable cannula & obturator, disposable seal)

Each configuration is made available in numerous diameters and lengths with either smooth or ribbed cannula for additional abdominal retention. Reusable cannulae and dilating obturators are supplied non-sterile and must be sterilized prior to use (Refer to "Reprocessing of Multi-use Components" in the Directions for Use). Also, see OnePort® Surgical Trocar System sales literature for a complete list of available sizes.

Indications for Use

The OnePort® Surgical Trocar System has applications in a variety of endoscopic procedures to provide a means of abdominal entry and access for endoscopic instruments.

Nonclinical Performance

The OnePort® Surgical Trocar System was tested and passed all required functional and biocompatibility testing.

Conclusion

The OnePort® Surgical Trocar System is substantially equivalent to the following 510(k) cleared devices:

K924761	Reflex STR Trocar System	Richard-Allan Medical Industries
K933456	ConMed TroGard™ Blunt Tip Trocar System	ConMed Corporation
K952977	SABRE™ Multi-Use Trocar System	Endoscopic Concepts, Inc.
K001697	ConMed TroGARD® Finesse™ Trocar System	ConMed Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Corporation
% Intertek Testing Services
Mr. Jay Y. Kogoma
Senior Staff Engineer
2307 East Aurora Road
Twinsburg, Ohio 44087

DEC - 7 2007

Re: K073009
Trade/Device Name: ConMed OnePort® Surgical Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 16, 2007
Received: November 19, 2007

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) _____

Device Name: ConMed OnePort® Surgical Trocar System

Indications for use:

The **CONMED OnePort® Surgical Trocar System** has applications in a variety of endoscopic procedures to provide a means of abdominal entry and access for endoscopic instruments.

Prescription Use ___X___ and/or Over-the-counter Use _____
(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k070309